

Attorney Docket No.: DEX-0075  
Inventors: Macina and Sun  
Serial No.: 09/618,596  
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a polypeptide encoded thereby, in cells, tissues or bodily fluids in a patient; and

(c) comparing the periodically determined levels of the CSG with levels of the CSG measured in cells, tissues, or bodily fluid of a normal human control, wherein an increase in any one of the periodically determined levels of the CSG in the patient versus the normal human control is associated with a cancer that is progressing in stage and a decrease is associated with a cancer that is regressing in stage or in remission.

**REMARKS**

Claims 1-5 are pending in the instant application. Claims 1-5 have been rejected. Claims 1-5 have been amended. No new matter has been added by the amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

Claims 1-5 remain rejected under 35 U.S.C. § 112, second paragraph, a being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regards as the invention. Specifically, the Examiner suggests that the recitation of "hybridizing under stringent conditions" in claims 1-5 is vague and indefinite.

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Applicants respectfully disagree for reasons set forth in the amendment filed November 4, 2002.

However, in an earnest effort to advance the prosecution of this case, Applicants have deleted this phrase from the pending claims.

Withdrawal of this rejection under 35 U.S.C. § 112, second paragraph, and subsequent allowance of claims 1-5 is therefore respectfully requested.

#### Conclusion

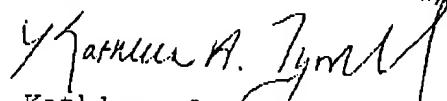
Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The

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attached page is captioned "Version with Markings to Show Changes  
Made."

Respectfully submitted,



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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Claims 1-5 have been amended as follows:

1. (four times amended) A method for diagnosing the presence of colon cancer in a patient comprising:
  - (a) determining levels of a colon specific gene (CSG) comprising a polynucleotide sequence of SEQ ID NO:1 or a polynucleotide which hybridizes under stringent conditions with SEQ ID NO: 1, or a polypeptide encoded thereby, in cells, tissues or bodily fluids in a patient; and
  - (b) comparing the determined levels of the CSG with levels of the CSG in cells, tissues or bodily fluids measured in a normal human control, wherein a change in determined levels of the CSG in said patient versus levels of the CSG measured in a normal human control is associated with the presence of colon cancer.
2. (thrice amended) A method of diagnosing metastases of colon cancer in a patient comprising:
  - (a) identifying a patient having colon cancer that is not known to have metastasized;
  - (b) determining levels of a colon specific gene (CSG) comprising a polynucleotide sequence of SEQ ID NO:1 or a

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~~polynucleotide which hybridizes under stringent conditions with SEQ ID NO: 1,~~ or a polypeptide encoded thereby, in cells, tissues or bodily fluids in a patient; and

(c) comparing the levels of the CSG determined in step (b) with levels of the CSG measured in a sample of cells, tissues or bodily fluid from a normal human control, wherein an increase in levels of the CSG determined in step (b) as compared to levels of the CSG measured in a sample of cells, tissues or bodily fluid from a normal human control is associated with a cancer that has metastasized.

3. (five times amended) A method of staging colon cancer in a patient having colon cancer comprising:

(a) identifying a patient having colon cancer;  
(b) determining levels of a colon specific gene (CSG) comprising a polynucleotide sequence of SEQ ID NO:1 ~~or a polynucleotide which hybridizes under stringent conditions with SEQ ID NO: 1,~~ or a polypeptide encoded thereby, in cells, tissues or bodily fluids in a patient; and

(c) comparing the levels of the CSG determined in step (b) with levels of the CSG measured in a sample of cells, tissues or bodily fluid from a normal human control, wherein an increase in the levels of the CSG determined in step (b) as compared to

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levels of the CSG measured in a sample of cells, tissues or bodily fluid from a normal human control is associated with a cancer that is progressing and a decrease in the levels of the CSG determined in step (b) as compared to levels of the CSG measured in a sample of cells, tissues or bodily fluid from a normal human control is associated with a cancer that is regressing or in remission.

4. (thrice amended) A method of monitoring colon cancer in a patient for the onset of metastasis comprising:

(a) identifying a patient having colon cancer that is not known to have metastasized;

(b) periodically determining levels of a colon specific gene (CSG) comprising a polynucleotide sequence of SEQ ID NO:1 or a polynucleotide which hybridizes under stringent conditions with SEQ ID NO:1, or a polypeptide encoded thereby, in cells, tissues or bodily fluids in a patient; and

(c) comparing the periodically determined levels of the CSG with levels of the CSG measured in cells, tissues or bodily fluid of a normal human control, wherein an increase in any one of the periodically determined levels of the CSG in the patient versus the normal human control is associated with a cancer that has metastasized.

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5. (thrice amended) A method of monitoring a change in stage of colon cancer in a patient comprising:

- (a) identifying a patient having colon cancer;
- (b) periodically determining levels of a colon specific gene (CSG) comprising a polynucleotide sequence of SEQ ID NO:1 or a polynucleotide which hybridizes under stringent conditions with SEQ ID NO: 1, or a polypeptide encoded thereby, in cells, tissues or bodily fluids in a patient; and
- (c) comparing the periodically determined levels of the CSG with levels of the CSG measured in cells, tissues, or bodily fluid of a normal human control, wherein an increase in any one of the periodically determined levels of the CSG in the patient versus the normal human control is associated with a cancer that is progressing in stage and a decrease is associated with a cancer that is regressing in stage or in remission.